Michael Ferronte

Summary of Statement

The American Society for Quality has a long history of cooperation and collaboration with the Agency. This is an organization whose primary goal is the promotion of quality and crosses many industries.

Past Issues

1. The Food, Drug, Cosmetic (FDC) Division of the ASQ has held joint conferences with the FDA to provide Regulatory and Quality updates on a regional basis. Conferences have been held in the Southeast, Northeast, Midwest, and West Coast on an annual basis. We have work with the FDA District Offices to promote education and training in these area and presently relevant topics covering CDER, CBER, and CDRH topics.

Examples are:

Annual regional FDA/FDC conferences concerned with compliance to current good manufacturing practices in association with the regional FDA offices

Seminars on current quality technology developments relating to the industry

Symposia on the legal responsibilities of quality professionals

Short courses for smaller groups requiring more comprehensive training

Future Areas

1. Presently the Division is working on the Certified Quality Auditor training and exam to expand it to encompass HACCP requirements. This exam, if successfully passed, will provide certification that an individual has mastered a core base of knowledge in HACCP. Input has been obtained from the Agency and hopefully the FDA will continue to participate.

2. Continue working with different District Offices and subject matter experts to hold conferences and workshops to provide timely training on new regulatory trends, technical trends, and basic compliance information. These are important training initiatives for our

membership and industry in general.

3. In the past our organization has been in the forefront of training activities by offering workshops on blood industry requirements and quality initiatives in the dietary supplement arena. We want to expand these effort with the Agency to have more interaction and FDA speakers to train the regulated industries.

4. It is one of the Division's goal to work with agency to ensure that they have another forum or outlet to present their messages to the industry. This serves both the Agency and our

membership.

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